Complete Summary

GUIDELINE TITLE

Abnormal uterine bleeding/dysfunctional uterine bleeding.

BIBLIOGRAPHIC SOURCE(S)

Abnormal uterine bleeding/dysfunctional uterine bleeding. Philadelphia (PA): Intracorp; 2005. Various p. [22 references]

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from July 1, 2005 to July 1, 2007.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, the U.S. Food and Drug Administration (FDA) asked manufacturers of prescription and non-prescription (over the counter [OTC]) nonsteroidal anti-inflammatory drugs (NSAIDs) to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the FDA Web site for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all NSAIDs make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Abnormal uterine bleeding, also called dysfunctional uterine bleeding

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Obstetrics and Gynecology
Surgery

INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, treatment, and management of abnormal uterine bleeding that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Women with abnormal uterine bleeding

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Physical examination and assessment of signs and symptoms
2. Diagnostic tests:
    - Urine pregnancy test or serum human choriogonadotropin (HCG)
    - Thyroid stimulating hormone (TSH) assay
    - Complete blood count (serum iron binding capacity [IBC], and ferritin and hemoglobin levels)
    - Ultrasound (US)
    - Coagulation studies (protime [PT}, partial thromboplastin time [PPT])
    - Checking progesterone levels mid-cycle
    - Thyroid function test, prolactin and androgen levels
    - Endometrial biopsy
    - Hysteroscopy
    - Sonohysteroscopy

Management/Treatment

1. Medical treatment
    - Oral contraceptives or cyclic progestin or estrogen regimens
    - Non-steroidal anti-inflammatory drugs (NSAIDs)
    - Antifibrinolytic agents
    - Danazol
    - Gonadotropin-releasing hormone (GnRH) agonists
    - Blood transfusions
2. Surgical treatment
    - Endometrial ablation
    - Dilation and curettage (D & C)
    - Hysterectomy
3. Referral to specialists

Note: Management of bleeding in pregnancy requires gynecologic referral and potential hospital admission especially if bleeding does not stop or is substantial and surgical intervention is required.

MAJOR OUTCOMES CONSIDERED

- Efficacy of medical and surgical treatment
- Complications of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The

Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Published cost analyses were reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnostic Confirmation

Subjective Findings

- Abnormal bleeding pattern or irregular bleeding cycles:
  - Bleeding between periods
  - Bleeding intervals that last greater than 35 days
  - Bleeding after months or years of amenorrhea
  - Bleeding that occurs less than every 21 days
- Pre-menopausal amenorrhea
- Menses that requires changing peri-pads or tampons hourly for several days' duration
- Symptoms related to dysfunctional uterine bleeding (DUB):
  - Abdominal cramping
  - Lightheadedness
  - Weakness
  - Nausea

Objective Findings

- Hypotension (includes orthostatic hypotension)
- Tachycardia
- Anemia (pale conjunctivae, mucous membranes, nail beds)

- Pelvic examination findings:
    - Blood in the vaginal vault
    - Blood coming from the cervical os
    - Blood from the vulva, vagina, or cervix
    - Fibroids or an ovarian mass (confirmed on ultrasound [US])

Diagnostic Tests

- Urine pregnancy test or serum human choriogonadotropin (HCG), to rule out pregnancy as the cause
- Thyroid stimulating hormone (TSH) assay
- Complete blood count
    - Serum iron binding capacity (IBC)
    - Ferritin level
    - Hemoglobin (Hgb) level
- Ultrasound (US)
- Coagulation studies (protime [PT], partial thromboplastin time [PTT])
- If cycles are very irregular or infrequent or if no mid-cycle temperature elevation is noted on daily temperature monitoring, bleeding may be secondary to anovulation or oligo-ovulation; this can be confirmed by checking progesterone levels mid-cycle.
- If bleeding associated with anovulation or oligo-ovulation, thyroid function tests, a prolactin level and androgen levels may identify a treatable cause of the ovulatory problem.
- Endometrial biopsy
- Hysteroscopy, which involves the direct visualization of the endometrium and may be followed by endometrial biopsy or ablation
- Sonohysteroscopy

Differential Diagnosis

- Thyroid, pituitary, or adrenal disease
- Polycystic ovarian syndrome
- Anorexia nervosa
- Excessive exercise or stress
- Reproductive tract disorders (abnormal pregnancy, ovarian tumors, uterine polyps or fibroids)
- Disorders of blood coagulation (von Willebrand's, idiopathic thrombocytopenic purpura, leukemia, cirrhosis)
- Medications (oral contraceptives, hormone replacement therapy, injected or implanted progestins, anticoagulants, or psychotropic drugs)
- Spontaneous abortion
- Malignancies (e.g., endometrial, cervical, and uterine cancer)
- Infection of the upper genital tract (e.g., endometritis)

Treatment

Treatment Options

NOTE: Management of bleeding in pregnancy requires gynecologic referral and potential hospital admission especially if bleeding does not stop or is substantial and surgical intervention is required.

- Treatment options include:
    - Oral contraceptives or cyclic progestin or estrogen regimens for patients with irregular cycles who are anovulatory or oligo-ovulatory
    - Non-steroidal anti-inflammatory drugs (NSAIDs) or oral contraceptives for heavy menstrual flow due to fibroids
    - Antifibrinolytic agents
    - Danazol
    - Gonadotrophin-releasing hormone (GnRH) agonists
    - Blood transfusions for blood loss resulting in compromised hemodynamic stability
    - Endometrial ablation
    - Dilation and curettage (D&C) if persistent bleeding or spontaneous abortion is incomplete
    - Hysterectomy

Duration of Medical Treatment

- Medical - Optimal: 7 day(s), Maximal: 10 day(s)
- Surgical - Optimal: 5 day(s), Maximal: 42 day(s)

Additional information regarding primary care visit schedules, referral options, and specialty care is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- Resolving bleeding without surgery or hospitalization
- After hospitalization with surgery (hysterectomy)
- After resolution of complications secondary to pregnancy (retained placenta)
- After resolution secondary to complications of malignancy

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis, treatment, and management of abnormal uterine bleeding that assist medical management leaders to make appropriate benefit coverage determinations

POTENTIAL HARMS

- Complications of hysteroscopic endometrial ablation include fluid overload, uterine hemorrhage, uterine perforation, thermal damage to adjacent organs, and hematometra.
- Radical hysterectomy carries with it a greater risk for bowel and bladder dysfunction, ureteral injury and subsequent urinary fistula.
- There may be a long-term risk for endometrial cancer after supracervical hysterectomy
- Many studies show that laparoscopy-assisted vaginal hysterectomy has higher rates of complication, longer operative times, and higher costs than simple abdominal or simple vaginal hysterectomy.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Intracorp

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Intracorp guidelines are available for a licensing fee via a password protected, secure Web site at www.intracorp.com.

Reprints of complete guideline content may be purchased for $35.00 per title (plus tax in TX at 8.25% and CT at 1.0%). Please send e-mail request to lbowman@mail.intracorp.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.
- Online guideline user trial. Register for Claims Toolbox access at www.intracorp.com.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on August 9, 2005. The information was verified by the guideline developer on August 31, 2005.

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DISCLAIMER

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